PRESOLICITATION NOTICE

PRE-CLINICAL MODELS OF INFECTIOUS DISEASES
RFP-NIAID-DMID-NIH-AI-2016059

Type of Requirement

☐ New Requirement
☒ Follow-on

Place of Performance

☒ Place of performance is unknown at this time
☐ Place of performance is known. Address or general location:_____

Recompetition

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, National Institutes of Allergy and Infectious Diseases, Office of Acquisitions, 5601 Fishers Lane, Room 3D47, MSC9821
For USPS mail, use: Bethesda, MD 20852-9821
For FedEx, UPS and other courier services, use Rockville, MD 20852

Email: brian.madgey@nih.gov

Duration of contract: 7 year Ordering Period

Anticipated award date: April 2017

Presolicitation Notice Information

Introduction

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), of the Department of Health and Human Services (DHHS) supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious and immune-mediated diseases. The NIAID, Division of Microbiology and Infectious Diseases (DMID) has a requirement to provide and develop animal models in order to advance our understanding of infectious diseases as well as advance the development of therapeutics and vaccines for infectious diseases.

Description

The National Institute of Allergy and Infectious Diseases (NIAID) supports and facilitates research that focuses on understanding, treating and, ultimately, preventing infectious, immunologic, and allergenic diseases that threaten the lives of millions of people. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports and facilitates research to understand, control and prevent human disease caused by infectious agents. Basic, applied and translational research to develop and assess therapeutics, vaccines, and diagnostics is supported through research grants, cooperative agreements, and contracts. In turn, DMID further supports and facilitates research ongoing under these funding mechanisms and through other programs via an array of preclinical and clinical resources and services in an effort to support multiples stages of the product development pipeline. These resources and services include genomic and gene sequencing services, provision of high quality biological materials, biocontainment facilities, and pre-clinical and clinical translational research resources (http://www.niaid.nih.gov/labsandresources/resources/dmid/Pages/default.aspx).

The current NIAID Animal Models of Infectious Diseases program is one of DMID's preclinical services resources and has supported the development and refinement of several animal models of infectious diseases, models that have been used subsequently to evaluate candidate medical countermeasures against these diseases. In addition, these contracts have facilitated regulatory submissions, patents, and other intellectual property applications by extramural investigators requesting evaluation of their products under these contracts. This program also has served the DMID mission of supporting investigator-initiated research by providing critical data needed to apply for grant or other funding. Finally, these contracts have enabled product developers and sponsors to make key go/no-go decisions for candidate therapeutics, vaccines, and diagnostics. In addition to meeting the needs of extramural researchers, this program has provided crucial data to be used by our partners at other agencies in the Department of Health and Human Services (DHHS). Such data facilitates the advancement of promising candidate medical countermeasures against priority bioterror agents to approval or licensure, and, in some cases, eventual deposit in the Strategic National Stockpile.

As background, in 2010, 38 institutions were awarded base contracts under the Animal Models of Infectious Diseases Indefinite-Delivery/Indefinite-Quantity (IDIQ) contract program. This program integrated services that had been provided via a number of smaller stand-alone contracts: In Vitro and Animal Models for Emerging Infectious Diseases and Biodefense, Tuberculosis (TB) Vaccine Testing and Research Materials, Animal Models for Prevention and Treatment of Hepatitis B & C, Animal Models of Human Viral Infection for Evaluation of Experimental Therapeutics, Schistosomiasis Research Reagent Resource Center, and Filariasis Research Resource Center. In addition to incorporating the objectives of these individual contracts, the overarching goal of the Animal Models of Infectious Diseases contract was to provide capability in a broad range of animal models for use in evaluating promising candidate countermeasures (vaccines, therapeutics, diagnostics) against the more than 270 infectious agents that are in the purview of DMID. The amalgamation of animal model programs has allowed cost savings and deletion of redundant activities, and the breadth of the existing contractor pool has enabled a rapid and effective response to emerging infectious disease and emergency preparedness priorities.

Awarded contracts were divided into 4 model-specific pools:

Part A – Small animal models of infectious diseases
Part B – Small animal models of infectious diseases – with the capability to conduct studies compliant with regulations set forth in 21CFR58: Good Laboratory Practices
Part C – Non-human primate models of infectious diseases
Part D – Non-traditional animal models of infectious diseases

Going forward, the Preclinical Models of Infectious Diseases program will include non-traditional animal models as well as models that could serve as replacements for animals in product screening and efficacy studies. The program will continue to provide the capability and capacity to develop and employ animal and animal replacement models (e.g., organ-on-a-chip technology) of infectious diseases for screening and product evaluation and address a critical stage in this pipeline by bridging *in vitro* testing and eventual clinical evaluation, including, as needed studies conducted under the guidance of 21 CFR 58, "Good Laboratory Practices". In addition, for candidate products that are unable to be assessed for clinical efficacy in phase II or III trials for ethical or practical reasons, contracts awarded under this solicitation will enable regulatory approval or licensure via the guidance of the Food and Drug Administration's (FDA) *Animal Efficacy Rule* (21 CFR 314.610 and 601.91).

This solicitation will award multiple IDIQ base contract awards to successful Offerors proposing a general approach to the requirements under one Contractor pool. Successful Offerors will have qualified for the pool to compete for eventual task order awards in one or more of the following areas:

Task Area A – Small Animal Models of Infectious Diseases
Task Area B – Non-Human Primate Models of Infectious Diseases
Task Area C – Non-traditional and Animal Replacement Models of Infectious Diseases

Contracts are anticipated to organizations proposing the full suite of services and also to organizations proposing one or more of the Task Areas.

For the purposes of this solicitation, the following definitions apply:

Model development: a novel systematic effort to reproduce a clinical syndrome caused by an infectious agent in an animal species following challenge with the agent, and will include median lethal and/or infectious dose determination, natural history of infection, and serial pathogenesis studies.

Model refinement: a systematic effort to improve the performance of an existing animal model that reproduces a clinical syndrome caused by an infectious agent; to adapt an existing animal model that reproduces a clinical syndrome caused by one infectious agent to a different, but related, infectious agent; to adapt an existing animal model to optimize its ability to support product screening or evaluation following challenge with the infectious agent.

Screening: encompasses early-stage or first-in-animal testing for product effectiveness in animals; activities include rudimentary testing of product effectiveness after challenge, determination of maximum tolerated dose, and minimum effective dose.

Evaluation: encompasses advanced testing after a product has been screened and demonstrated as efficacious in the same or lower animal models; activities include dose refinement, measurement of host response, pharmacokinetics, pharmacodynamics, and protection against challenge.

Small animal models: includes traditional laboratory rodent species (mice, rats, hamsters, gerbils (including jirds), guinea pigs); transgenic, humanized knock-out, and knock-in mouse strains; cotton rats; laboratory rabbit varieties; and laboratory ferrets.

Non-human primate models: new and old world species, including *Macaca, spp.* (cynomolgus, Rhesus, pig-tailed); *Chlorocebus, spp.* (African green monkeys, vervets); *Aotus, spp.*; *Papio, spp.*; *Callithrix, spp.* (marmosets).

Non-traditional animal models: includes:

- Domestic livestock: horses, cattle, goats, sheep, pigs, chickens, domestic fowl
- Wildlife species: marmots, deer, bats
- Companion species: dogs, cats
- Invertebrates: snails, non-parasitic nematodes, insect vectors of human disease
- Aquatic: zebrafish
- Animal replacement: organs on chips, artificial complex cell systems

Products: prevention agents such as vaccines or microbicides; therapeutics targeting the host or the pathogen, including conventional drugs, immunotherapeutics, and therapeutic vaccines; and diagnostics.

Pathogens: infectious bacteria, viruses, parasites, fungi, toxins, and other agents such as prions that cause clinical syndromes in humans (surrogate human pathogen/animal combinations may be used for diseases where human pathogens cannot be studied in animal models)

Reagents: biochemical, genomic, molecular, cellular, and immunologic materials integral to research on these pathogens, including the pathogenic agent or toxin itself; these may be required to be generated to support a study or as a deliverable.

The services shall be directed at the following:

Small animal models

Non-human primate models

Non-traditional animal models

Model species that are not listed with the individual Task Areas above, but are requested for development or demonstrated as necessary for testing medical countermeasures following award, will be taken under advisement by the Government, and task order requirements involving these model species may be developed on a case by case basis as long as they are determined to represent benefit to the Government.

The services shall be directed at all infectious agents except Human Immunodeficiency Virus (HIV), with special emphasis on the following areas:

- Antimicrobial resistant and multi-drug resistant infections, including Methicillin-Resistant *Staphylococcus aureus*, Vancomycin-Resistant *Enterococcus*, Carbapenem-Resistant *Enterobacteriaceae, Acinetobacter baumanii*, *Pseudomonas aeruginosa*, and *Clostridium difficile*
- Diseases caused by pathogens and toxins on the National Institute of Allergy and Infectious Diseases (NIAID) Emerging Infectious Diseases/Pathogens list (http://www.niaid.nih.gov/topics/biodefenserelated/biodefense/pages/cata.aspx): in particular, influenza, viral hemorrhagic fevers (including arthropod-borne viruses), arthropod-borne encephalitis viruses, rabies, *Mycobacterium tuberculosis* (including Multidrug-resistant (MDR) and Extensively drug-resistant (XDR) strains), *Bordetella pertussis,* Group A Streptococcus, *and Coccidioides;*
- Non-Biodefense Bacteria, including non-tuberculous *Mycobacterial spp.*, *Streptococcus pneumoniae*, Mycoplasma pneumonia, Chlamydophila pneumonia, *Haemophilus, spp.*, and *Legionella, spp.*;
- Non-Biodefense Viruses, including: Respiratory syncytial virus (RSV), human metapneumovirus, parainfluenza virus, Hepatitis B and C viruses, Herpesviruses (Herpes simplex virus (HSV) 1 and 2, cytomegalovirus (CMV), varicella-zoster virus (VZV), human herpesvirus (HHV)-6/7); papillomaviruses; enteroviruses; adenoviruses;
- Fungal diseases, including invasive aspergillosis, candidiasis, cryptococcosis, mucormycosis , pneumocystis pneumonia;
- Neglected tropical diseases, including: filariasis, trachoma, leprosy, schistosomiasis, and trichomoniasis; and
- Sexually transmitted infections, including: chlamydia, bacterial vaginosis, and gonorrhea

The NIAID recognizes that a single organization or institution may not have the full spectrum of expertise or facilities required to perform all activities set forth in the Statement of Work. Contractors shall perform the work described in *one or more* Task Areas. Contractors may need to be supported to a certain extent by the expertise and resources of other organizations or persons through consortia agreements, partnerships, subcontracts, and/or consultants. However, contractors shall be responsible for ALL work performed and shall be responsible for project planning, initiation, implementation, management and communication; evaluation, selection, and management of subcontractors; and for all deliverables specified in this contract and each awarded Task Order.

Any responsible Offeror may submit a proposal which will be considered by the Agency. The Request For Proposal (RFP) will be available electronically on/about May 13th, 2016 and may be accessed through FedBizOpps http://www.fedbizopps.gov/. This notice does not commit the Government to award a contract. No collect calls will be accepted. No facsimile transmissions will be accepted.

For this solicitation, the NIAID requires proposals to be submitted via two methods: (1) Disc (CD or DVD) and (2) Online via the NIAID electronic Contract Proposal Submission (eCPS) website. The content of the disc and online proposals must be identical. Submission of proposals by facsimile or e-mail is not acceptable.

For directions on using eCPS, go to the website https://ecps.niaid.nih.gov and then click on "How to Submit."

To submit online using eCPS, offerors must have a valid NIH electronic Research Administration (eRA) Commons account, which provides authentication and serves as a vehicle for secure transmission of documents and communication with the NIAID. The eRA Commons registration process may take up to 4 weeks. For more information, please see http://era.nih.gov/applicants/how-to_steps.cfm#register."